
A Phase 2 Open-Label, Multi-Center, Randomized, Controlled, Optimal Dose-Finding Study of DCC-UCB in Adults Receiving High Dose Chemotherapy for AML

Grant Award Details

A Phase 2 Open-Label, Multi-Center, Randomized, Controlled, Optimal Dose-Finding Study of DCC-UCB in Adults Receiving High Dose Chemotherapy for AML

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-09574

Project Objective: Carry out a Phase 2 dose-finding clinical trial of a cord blood-derived product, NLA101, in AML patients with Chemotherapy-induced Neutropenia.

Investigator:

Name:	Colleen Delaney
Institution:	Nohla Therapeutics Inc
Type:	PI

Disease Focus: Blood Cancer, Cancer, Acute Myeloid Leukemia

Award Value: \$6,922,109

Status: Active

Grant Application Details

Application Title: A Phase 2 Open-Label, Multi-Center, Randomized, Controlled, Optimal Dose-Finding Study of DCC-UCB in Adults Receiving High Dose Chemotherapy for AML

Public Abstract:**Therapeutic Candidate or Device**

Cryopreserved, universal donor hematopoietic stem cell therapy that restores blood cell function and protects against infection after chemotherapy

Indication

Neutropenia arising from high-dose chemotherapy for treatment of Acute Myeloid Leukemia

Therapeutic Mechanism

The primary treatment for patients with AML is chemotherapy. Most chemotherapy results in a period of neutropenia (very low white blood cell counts) when patients are at significant risk of developing life threatening infections, sepsis and related complications. The intended cell therapy provides a source of functional early blood cells that can generate mature and functionally intact white blood cells in the patient for the prevention of infections and sepsis following chemotherapy.

Unmet Medical Need

There are an estimated 500,000 courses of high dose chemotherapy administered globally each year and despite improved antimicrobials for patients who experience febrile neutropenia or documented infections, 15%-20% of patients will go on to have uncontrolled, severe infections.

Project Objective

Phase 2 trial completed, CSR generated

Major Proposed Activities

- Preparation for scale-up of DCC-UCB GMP manufacturing
- GMP manufacturing of DCC-UCB for clinical use
- DCC-UCB Phase II study for the treatment of chemotherapy induced neutropenia in AML patients.

Statement of Benefit to California:

The Ph2 trial for this novel therapy will greatly impact outcomes and quality of life for the 1,600 CA/20,000 US patients/year undergoing treatment for AML. Despite improved antimicrobials, many neutropenic patients will go on to have uncontrolled, severe infections that result in increased ICU admissions death. This therapy will immediately benefit CA patients at the 5-8 California sites and the manufacturing and depot facilities at UC Davis will provide an economic benefit for the state.

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